Development and Leak Testing of 3D Modeled Custom Made Non-Invasive Positive Pressure Ventilation Masks for Children

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Background

Fit of commercially available non-invasive positive pressure ventilation (NIPPV) masks is challenging in infants and children. With limited pediatric sizing, poor mask fit may cause mask leak, discomfort, skin injury and facial deformity by necessitating excess pressure to achieve an adequate seal. This may decrease efficacy and compliance. Custom masks may have utility in children with poor fit with commercial masks.

Our goal was to further develop a process to customize NIPPV masks and to evaluate the impact of mask material and type on unintentional leak for varying continuous positive airway pressures (CPAP).

Mask Development

Custom masks were designed using a four stage process based on computerized tomographic (CT) facial images of a 6 year old subject.

Figure 1:
The CT images were converted into a three-dimensional (3D) model using Mimics Innovation Suite software.

Figure 2:
The custom mask interface was created using Rhinoceros modeling software by subtracting the facial surface from a generic mask form.

Figure 3:
The mask mold was printed by the Objet30 3D printer in a resin-like material. Custom masks were poured and cured in various densities of medical grade silicone. A custom mask casing was 3D printed in medical grade polymer for the soft durometer mask.

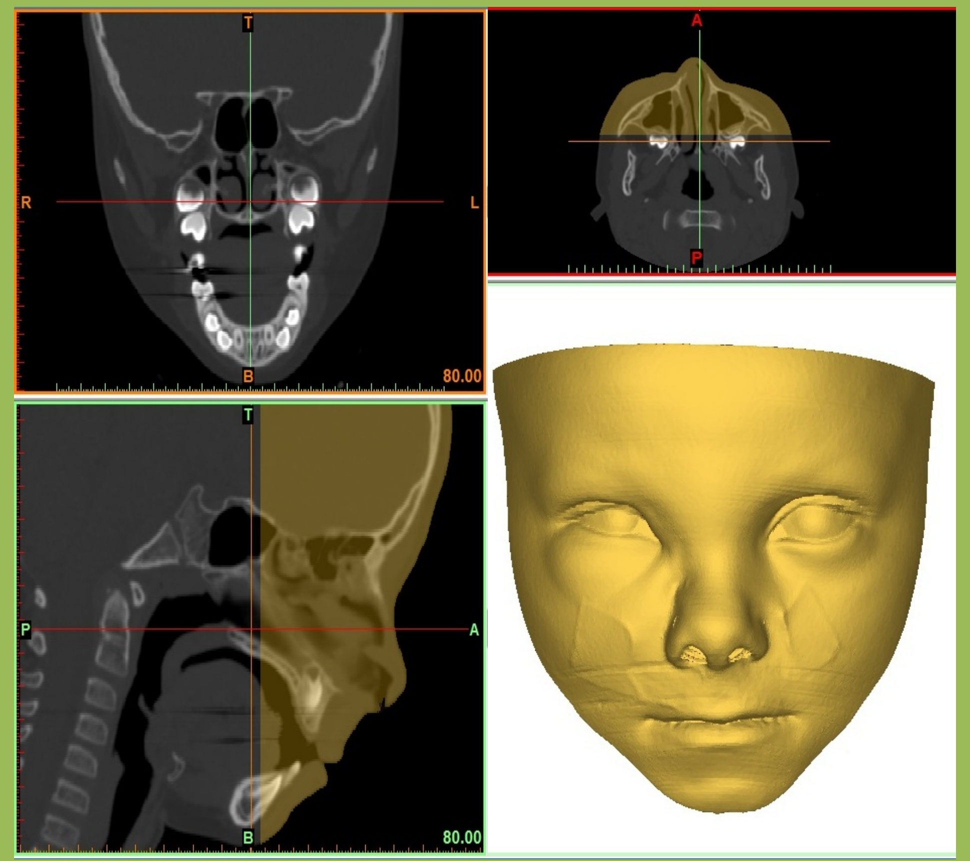

Figure 1

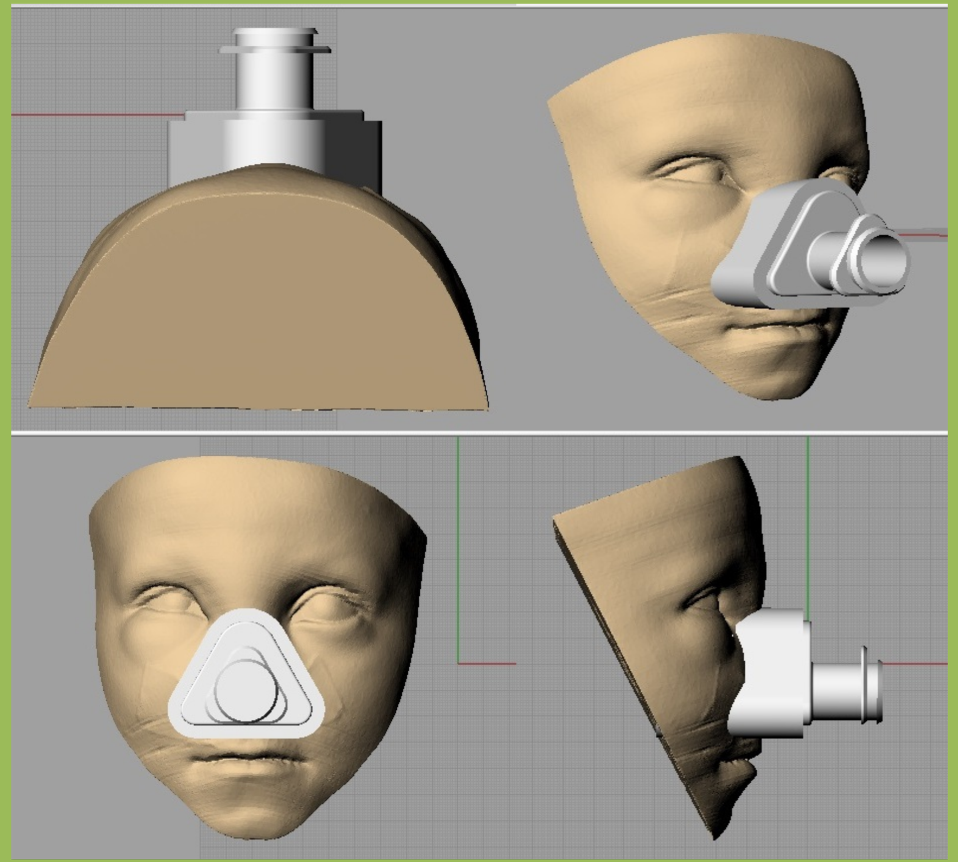

Figure 2

Figure 3

Leak Testing

For laboratory testing, a 3D acrylonitrile butadiene styrene (ABS) facial model of the 6 year old subject, which had been developed from CT images, was used.

The model was fit with two appropriate commercial masks by a clinical specialist (Wisp, Philips Respironics [Commercial 1]; Eson, Fisher and Paykel [Commercial 2]). Two custom masks of hard (Custom 1) and soft (Custom 2) durometer medical grade silicone were produced.

A stand was constructed to stabilize the mask (figure 4). Flow rates were regulated by mass flow controller (Alicat Scientific) to achieve 5 and 10 cm H_2O of CPAP, as measured by digital manometer (Omega). Weights varying from zero to 1000 grams were applied to each mask to create a seal(Figure 5 and 6) and unintended leak was measured. Five tests of each condition were performed.

Intended leak rate through the expiratory valve was determined under fully sealed conditions.
Unintended leak rate was determined from excess flow above the intended leak rate required to maintain CPAP.

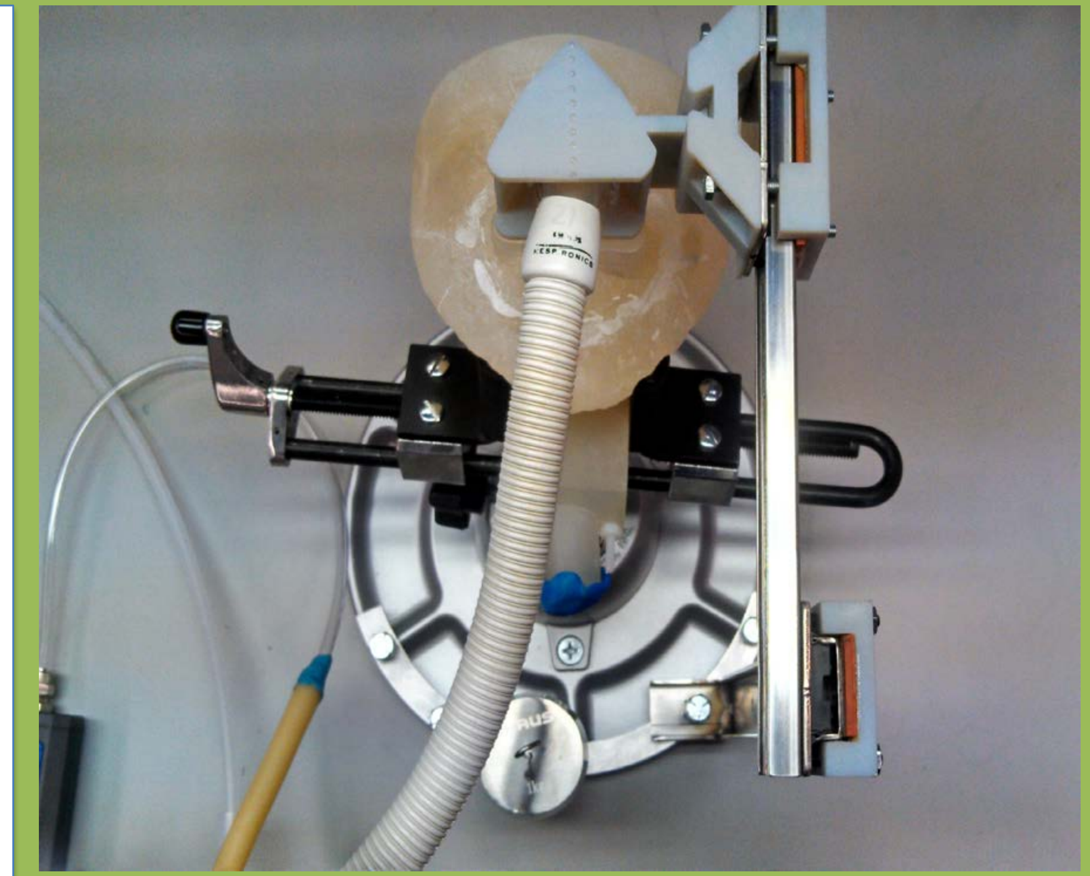

Figure 4

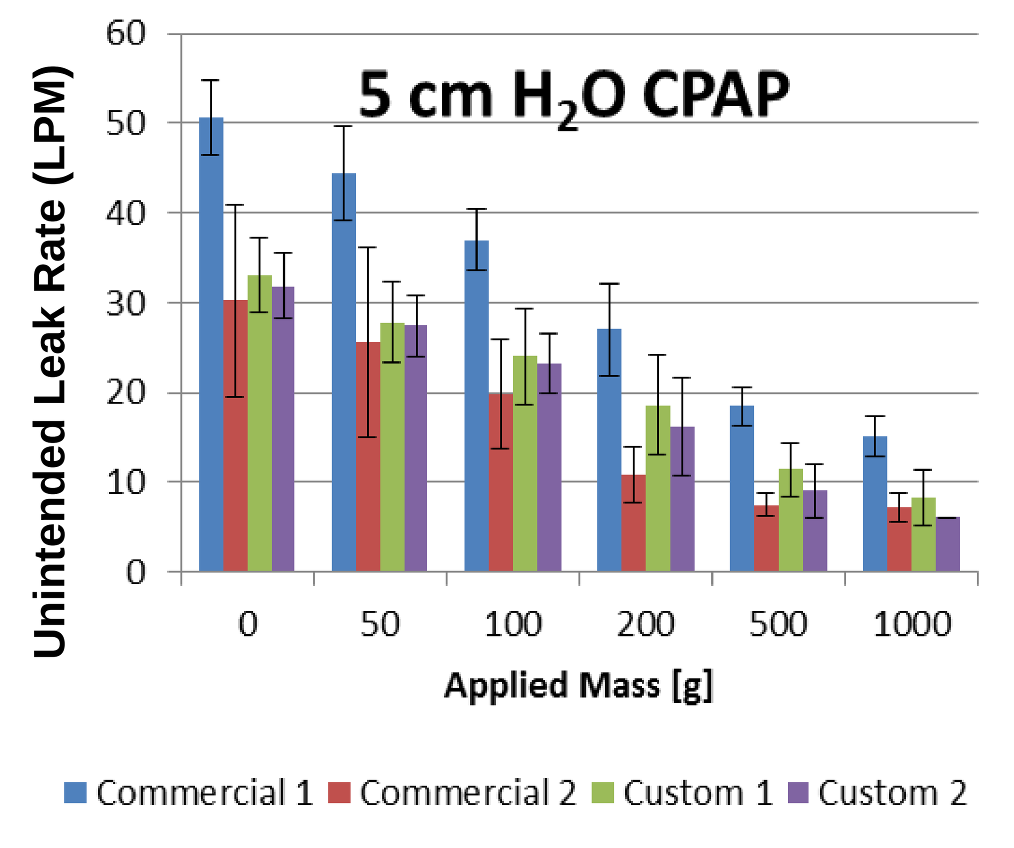

Figure 5

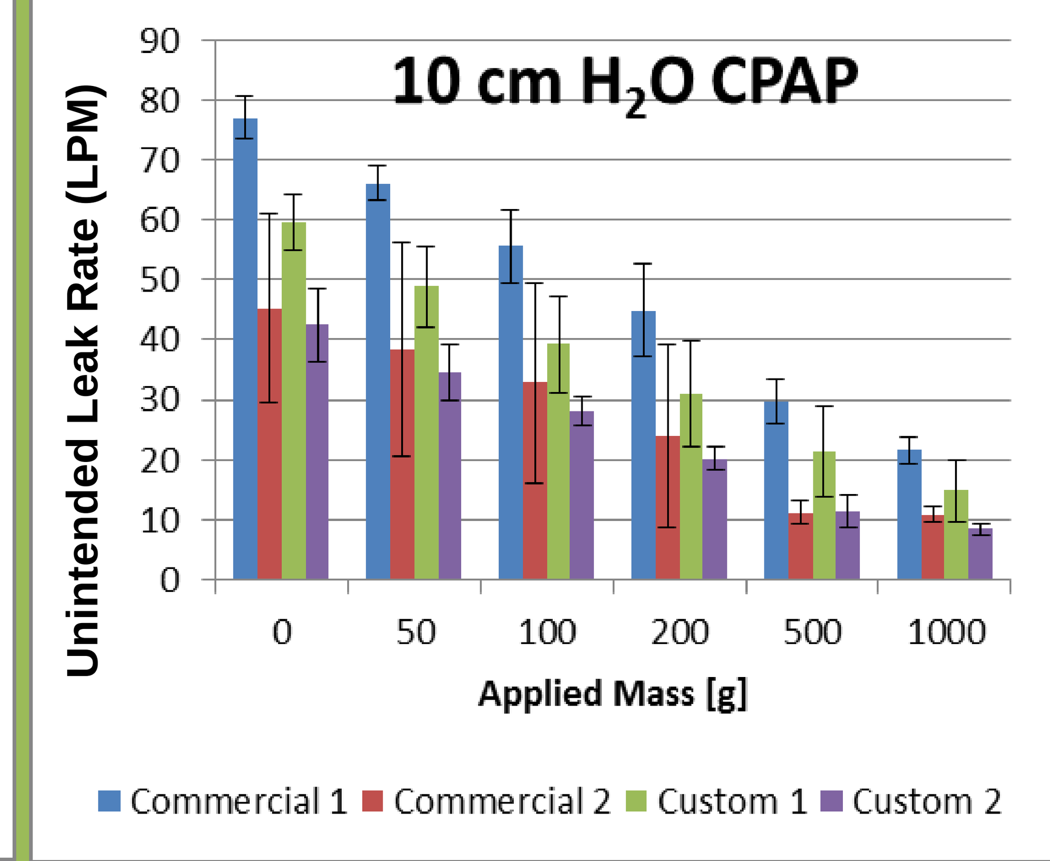

Figure 6

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Results

Intended leak rate was consistent between all masks. The custom masks had significantly lower unintended leak rates than Commercial 1 for the majority of applied weights at 5 and 10 cm H20 ($p<0.01$). Commercial 2 had similar leak rates to the custom masks, with the softer custom mask (Custom 2) trending lower at 10 cm H20. The custom masks showed less variability between trials compared to Commercial 2.

Conclusions

We have developed a process for the rapid production of customized NIPPV masks using 3D imaging.

Our custom masks have similar or decreased unintentional leak and less variability between trials than commercial masks.

We will use this data to optimize the design and materials of customized NIPPV mask, prior to clinical testing of custom masks in children.